K073377

ACL TOP System Software V3.0.0
510(k) Summary

MAY 14 2008

Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	113 Hartwell Avenue Lexington, MA 02421
Contact Person:	Carol Marble, Regulatory Affairs Director
Phone Number:	781-861-4467
Fax Number:	781-861-4207

Preparation Date: February 4, 2008

Device Trade Name:

ACL TOP

Regulatory Information:

Regulation Section:	Coagulation Instrument (864.5400)
Classification:	Class II
Product Code:	GKP
Panel:	Hematology

Predicate Device:

K063679	ACL TOP

Device Intended Use / Description:

The ACL TOP is a bench top, fully automated, random access analyzer designed specifically for *in vitro* diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.

The system provides results for both direct hemostasis measurements and calculated parameters.

Reason for Submission:

System Software V3.0.0 is being introduced on the ACL TOP family (instrument available with and without the feature of closed tube sampling) to support the conversion from the Windows 2000 Operating System to the Windows XP Operating System. This software also includes additional features and ease-of-use enhancements.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The performance of the ACL TOP family with System Software V3.0.0 is substantially equivalent to the performance of the current legally marketed ACL TOP (K063679).

- There are no changes in the ACL TOP test parameters (which are separate from the system software) and therefore, no changes to the labeled indications for use/intended use or performance claims of either the instrument or its reagents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 2008

Instrumentation Laboratory Co.
C/O Carol Marble
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: k073377
Trade/Device Name: ACL TOP (with System Software V3.0.0)
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation instrument
Regulatory Class: Class II
Product Code: GKP
Dated: November 30, 2007
Received: December 3, 2007

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K073377

Device Name: ACL TOP Family

Indications for Use:

The ACL TOP is a bench top, fully automated, random access analyzer designed specifically for *in vitro* diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.

The system provides results for both direct hemostasis measurements and calculated parameters.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K073377